



Hearing Testimony  
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On Behalf Of  
The Biotechnology Industry Organization

Before the Government Reform Subcommittee on Regulatory Affairs  
U.S. House of Representatives  
Field Hearing

“A Balancing Act: Cost, Compliance, and Competitiveness after Sarbanes Oxley”

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Chairwoman Miller, Ranking Member Lynch, and the Members of the Government Reform Subcommittee on Regulatory Affairs:

Thank you for providing the opportunity to testify before you today on Sarbanes-Oxley Act (SOX) Section 404 and finding the proper balance among cost burdens, investor protection and U.S. competitiveness.

My name is David Lawrence, Chief Financial Officer of Acorda Therapeutics, a public biotechnology company in Hawthorne, New York. I have been involved with the management of corporate governance and finances in biotech and high-tech companies for over 15 years. Founded in 1995, Acorda is a biotechnology company focusing on the development of next generation therapies that restore neurological function to people with spinal cord injury (SCI), multiple sclerosis (MS) and related conditions of the nervous system. Acorda's products, Zanaflex Capsules™ and Zanaflex® tablets, are FDA-approved for the management of spasticity, a symptom of conditions such as MS and SCI that is commonly characterized by stiffness or rigidity, restriction of movement and painful muscle spasms. Our Company has clinical and pre-clinical drug candidates for MS that focus on novel approaches to repairing damaged components of the central nervous systems. We are currently a net loss company with one drug on the market and our market capitalization is at the bottom 0.5% of total U.S. market capitalization of \$76 million as of June, 2006. We have completed our initial public offering in February, 2006, and are currently beginning the process of complying with the Sarbanes-Oxley Act.

Today, I am here to testify on behalf of the Biotechnology Industry Organization (BIO), an organization representing more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations in 50 U.S. states and 31 other nations. BIO members are involved in the research and development of health care, agricultural, industrial, and environmental biotechnology products. The majority of BIO member companies are small, research and development oriented companies pursuing innovations that have the potential to improve human health, expand our food supply, and provide new sources of energy. My Company has a profile that is typical of the high-risk, capital-intensive, long lead-time, regulated business environment of the biotech industry.

As a representative of one of the most innovative high growth sectors of our nation's economy -- one in which the United States maintains a global leadership position—my testimony is tailored to the issues faced currently, or that will be faced, by emerging companies in the biotech sector – the microcap and smallcap companies who are among the driving forces of our country's innovation leadership and competitiveness in the global market place.

#### One Size Does Not Fit All

Let me start by saying that we fully appreciate and agree with the Congressional intent behind Section 404 – to enhance investor protection and confidence. BIO members strongly support this goal. In fact, it should be the goal of all public companies – small or large – to operate in a way that is transparent, is subject to high standards of corporate governance, and enhances investor and shareholder confidence. The vast majority of public companies of all sizes has done so, and continues to do so today.

Where Section 404 has gone awry is in the implementation of the requirements. The current implementation of Section 404 is not tailored, and does not work well, for smaller public companies. The one-size-fits-all approach of Section 404 is highly burdensome to smaller companies, and such companies are bearing disproportionate costs on a relative basis. This has been recognized, and documented, by the SEC Advisory Committee for Smaller Public Companies (Advisory Committee), who voted overwhelming in favor of reform by an 18-3 vote in April, 2006. In its Final Report, the Advisory Committee found that, “with more limited resources, fewer internal personnel and less revenue with which to offset both implementation costs and the disproportionate fixed costs of Section 404 compliance, [small] companies have been disproportionately subject to the burdens associated with Section 404 compliance.”

The U.S. Government Accountability Office (GAO) also made similar findings in its May, 2006, report stating that smaller public companies at the bottom 6% of total U.S. market capitalization pay up to \$1.4 million on external auditors for Section 404 compliance. In fact, 47% of the companies reported that Section 404 compliance resulted in significant “opportunity costs” by draining resources away from innovation and research.

Even the SEC recognizes that Section 404 needs reform, based on its recent May roundtable discussions regarding Section 404 year two compliance. In fact, the SEC announced in May regarding its intention to review current Section 404 requirements and to provide necessary reforms based on a top-down, risk-based, and scaled approach, which would be more responsive to the individual size and complexity of the companies.

There is agreement among the SEC, its Advisory Committee, and the GAO that Section 404, as currently implemented, fails to scale regulatory burdens on a cost-benefit basis and disregards the levels of product revenues and the complexity of corporate structures, which drive the need for corresponding levels of internal controls.

Simply put, if the current Section 404 implementation continues to be imposed, or, in the case of non-accelerated filers, is imposed in the future, microcap and smallcap companies in our industry will be required to implement internal processes and organizational changes that are completely contrary to the rapidly changing and highly-competitive markets in which we operate.

#### The Costs of the One-Size-Fits-All Approach to the Industry and U.S. Competitiveness

For most biotechnology companies, the actual costs of Section 404 compliance, including both internal costs as well as external auditor costs, are substantial. In fact, the opportunity costs of Section 404 for smaller companies can be even greater, impeding the ability to invest in and sometimes, to continue ongoing, critical research and development activities. Biotech companies are at the forefront of developing new treatments for many diseases, and biotech companies presently are engaged in over 350 clinical trials for over 200 diseases, from cancer to multiple sclerosis.

Under the requirements of Section 404, significant time and money are spent to put in place complex systems and processes dictated by the Auditing Standard No. 2 (AS2) and required by external auditors. If the current system is not changed, these effects will also be felt by non-accelerated filers as they prepare for compliance by the end of next year, as well as private companies preparing for an initial public offering of their stock.

As a specific example, one of BIO's member companies had five employees working on Section 404 compliance at a cost of approximately \$1 million per year. This company estimated that its controller spent approximately 35% of his time on Section 404, while the CFO spent approximately 20% of his time. To complete the mandated internal control processes and the "checklist" dictated by AS2, the company had to increase its accounting staff by 40%. Further, this company reports only a 7% decrease in costs in year two as compared to its first year of compliance.

Another member company's experience shows the opportunity costs of Section 404 compliance. This company not only spent approximately \$500,000 on its external attestation of internal controls but also had to endure additional costs in terms of (i) the reassignment of laboratory research personnel to perform internal control work dictated by AS2 and the company's external auditors, (ii) the postponement of the hiring of 5-10

additional researchers, and (iii) the delay of promising R&D programs. Such diversion of resources away from research activities can delay critical product development and has, in turn, a detrimental effect on a company's ability to raise capital.

Our experience, as a newly public company is very similar to those experienced by BIO member companies. Due to limited internal resources, we will have to immediately contract with an outside consulting firm in order to comply with SOX requirements by the 2007 deadline. We will be facing the same SOX related expenses similar to that of other biotech companies. For many of the newly public companies, Section 404 costs could mean having to spend a large portion of their research funding for a leading drug or therapy on Section 404 compliance -- forcing many of the companies to make reductions in research spending in order to meet the regulatory requirements imposed by Section 404.

It is also the experience of BIO members that the current problems with Section 404 are not merely growing pains where the costs and burdens will decrease once the auditors and companies become more familiar with the process and requirements. The current implementation of Section 404 imposes the same requirements, steps and reviews on all companies, by the same individuals year after year. As a result, the costs are fixed and ongoing, impacting the long-term investment resources of microcap and smallcap companies.

For the investors, their confidence and trust in public companies may have increased as a result of the passage of SOX as a whole and not necessarily due to Section 404. The other provisions in SOX include whistleblower protections, increased enforcement powers, such as the SEC's increased ability to obtain officer and director bars, auditor independence requirements and, perhaps most importantly, CEO and CFO certifications of company financial statements under section 302 of SOX. As we saw in the first and second years of Section 404 implementation, investors and the market generally had little market reaction when a company reported a "material weakness" in internal controls under Section 404.<sup>1</sup> As we discussed further above, the costs of the implementation of Section 404, particularly for smaller public companies, appear to outweigh many of the benefits that are directly related to Section 404.

The impact of Section 404 costs on the U.S. economy and our industry's competitiveness abroad is also of great concern. As many Members on the Subcommittee may have undoubtedly heard and read, there is evidence that foreign firms, the largest of which will be subject to Section 404 compliance beginning July 15, 2006, are foregoing the U.S. markets and listing overseas due, in large part, to Section 404, not necessarily because of SOX in general. In fact, the SEC Commissioner Atkins in his letter to the Wall Street Journal on June 10, 2006, indicated that last year, nine out of every ten dollars raised by non-U.S. companies through new stock offerings were issued overseas, while the reverse was true just six years ago in 2000. In addition, it is the experience of BIO's private

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<sup>1</sup> See, e.g., Neil O'Hara, *An Analysis of the (Non) Impact of SOX 404*, Compliance Week, March 8, 2005. In addition, at the 2005 SEC and PCAOB Roundtable on Section 404, a representative of Moody's on one of the panels stated that, of the 71 companies disclosing material weaknesses they considered in detail, they ultimately issued a negative rating action on 12, or 20%, of the companies. Thus, credit rating agencies had no adverse reaction to approximately 80% of the companies.

company members that an initial public offering is becoming less and less the optimum path to liquidity for their investors due to the timing issues associated with accessing the market while at the same time ensuring readiness for Section 404. This issue has been previously noted by the recently-appointed head of the Division of Corporation Finance at the SEC.<sup>2</sup>

### Scaled Reform Needed for Smaller Public Companies

As embraced by the Advisory Committee in its final recommendations, it is critical that the Section 404 reform framework establishes a risk-based approach that provides scaled reforms based on a “revenue filter” condition. This approach recognizes that the level of risk and the level of product revenues are clearly interrelated and that the level of product revenues should drive the complexity of internal control procedures. An approach that scales Section 404 requirements based on the level of product revenues also provides a risk-based approach, more appropriate for microcap and smallcap companies in our industry. Biotechnology start-up companies early in their histories often have very limited product revenues compared to their market capitalizations. For example, it is not uncommon for a public biotechnology company to have a market capitalization of \$700 million or greater with product revenues of \$1 million, or less.

BIO has urged the Securities and Exchange Commission (Commission) and the Public Company Accounting Oversight Board (PCAOB) to, as expeditiously as possible, take the necessary steps to adopt the following reform framework as endorsed by the Advisory Committee:

- Section 404 requirements should be “scaled” and “proportional” to the size of product revenues and complexity of corporate structures.
- Scaled reform should be based on the principle that the level of risk and product revenues are intricately tied, that product revenues drive the complexity of corporate structures and the corresponding need for more rigid and established internal control processes.
- Product revenue should be defined as product and services revenue, excluding revenues from license fees, research and development payments, milestone payments, and other payments received from an unrelated third party before product sales have commenced under the terms of a collaborative contractual agreement to develop a product.
- The internal controls necessary to meet Section 404 should be consistent with the level necessary to meet the CEO and CFO certifications of company financials as currently required under Section 302 of the Sarbanes-Oxley Act.

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<sup>2</sup> See, the letter from John W. White, the new and current head of the Division of Corporation Finance at the SEC, submitted in connection with the SEC’s 2005 Roundtable on Section 404, available at <http://www.sec.gov/news/press/4-497.shtml>.

The proposed reform framework supports the management's incentive to maintain effective and integrated systems of internal controls and produce accurate financial reports, most important to the investors. Section 13(b)(2)(B) of the Exchange Act requires, as it has since 1977, that public companies maintain a system of internal controls that provide reasonable assurances as to the accuracy of financial reports. This framework provides additional assurance to investors in a cost effective and risk based way to providing Section 404 relief for smaller public companies. Under SOX Section 302, each CEO and CFO must certify that the financial statements fairly present in all material respects the financial condition of the company, and they have disclosed all weaknesses in the internal controls which could be reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information, among other items.

As demonstrated above, without Section 404 reform, evidence points to the fact that innovation may be stifled and U.S. competitiveness compromised. With the recent submission of the Advisory Committee's final reform recommendations in April, and the SEC's announcement in May regarding its intention to take additional steps to reform Section 404, it appears that now is the opportune time for the SEC to fully engage and follow through with reforms consistent with the original principles upon which SOX was enacted.

Thank you for your time and consideration of BIO's views. BIO urges the Subcommittee to request expeditious action by the Commission on the reform framework endorsed by the Advisory Committee. These reforms are critical in providing the high growth sectors of the U.S. economy with the continued opportunity to lead, innovate, and compete in the global market place.